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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,913	03/16/2004	Katsuhiro Hiejima	NPR-154	9625
20374 7590 05/16/2007 KUBOVCIK & KUBOVCIK SUITE 710 900 17TH STREET NW WASHINGTON, DC 20006			EXAMINER STEPHENS, JACQUELINE F	
			ART UNIT 3761	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

6b

Office Action Summary	Application No. 10/800,913	Applicant(s) HIEJIMA ET AL.	
	Examiner Jacqueline F. Stephens	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 2/5/07 have been fully considered but they are not persuasive. Applicant argues Elias does not show the transferring passage extends through the entire longitudinal length. However, Applicant has not specified in the claims through which longitudinal length. The claim can be interpreted as the entire longitudinal length of the intermediate portion of the valve, etc. Applicant argues elements 18a are not branch portions. The Examiner has identified element 18 as equivalent to the spike of the present invention. Similarly, Applicant argues the helical spring of Elias, identified by the Office as being a plurality of divided bodies comprising the spike is not formed in one pair in axial symmetry. Figure 3 of Elias shows elements 18A as or, as broadly as claimed branches or divided bodies formed on element 18. Applicant has not set forth why these elements are deficient to describe the claimed invention. Applicant argues the spike has a solid structure. The Examiner maintains the spike is solid as broadly as claimed, as compared to a liquid structure.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 2-6 and 10-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Elias et al. USPN 5549566.

As to claim 2, Elias discloses a medical valve 12, to which a male luer is to be separably connected (col. 3, lines 57-58), comprising: (a) a housing 14 having a hollow body opened at the top end 24, wherein the tip of the male luer is to be removably inserted in the housing; (b) a spike 18 disposed to extend longitudinally in the housing, the spike except at least the top end portion being formed in an approximately tapered shape (Figures 1 and 2) in which its outside diameter becomes progressively smaller toward the top end portion, wherein a fluid transferring passage 68, which is opened radially outwardly, is formed to extend the entire longitudinal length in the peripheral surface of the spike, the bottom portion of the fluid transferring passage 66 being connected to a fluid circuit (col. 5, lines 43-45); and (c) an elastic seal 16 having an elastically deformable tubular shape fitted on the spike to seal the spike, the elastic seal comprising a top end portion 46 having an openable/closable portion 50 to be openably closed over the spike, wherein the elastic seal is elastically deformed to be downwardly shrunk by downward pressure due to the tip of the male luer, thereby the openable/closable portion 50 is brought into abutment with the spike, and is elastically deformed to be opened radially outwardly to be fitted onto the spike, so that the inside of the male luer communicates with the fluid transferring passage of the spike (col. 3, line 57 through col. 4, line 7; col. 4, lines 61-65). The limitations regarding compression of the seal is directed to an intended use of the article. Intended use must result in a structural difference between the claimed invention and the prior art in order to

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patentably distinguish the claimed invention from the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). If the prior art structure is capable of performing the intended use, then it meets the claim limitations.

Elias discloses a medical valve, see the rejection of claim 1, *supra*. Elias discloses a groove-shaped fluid transferring passage (Figures 1-4, defined by ribs 56).

As to claim 3, Elias discloses a medical valve, see the rejection of claim 1, *supra*. Elias discloses a joining portion 50a constituting the top end portion of the spike; and a plurality of branch portions 18a, which constitutes the remaining portion of the spike, formed integrally with the joining portion to branch off downwardly from the joining portion, and wherein the fluid transferring passage is defined between the branch portions (Figure 3).

As to claim 4, Elias discloses a medical valve, see the rejection of claim 1, *supra*. Elias discloses the spike 18 comprises a plurality of divided bodies 80 which are formed into one pair I axial symmetry and extend along the entire longitudinal length thereof, and wherein the fluid transferring passage 68 is defined between the divided portions (Figures 5 and 6).

As to claim 5, see the rejection of claim 1, *supra*. Elias discloses a plurality of main portions formed by ridges 56 (Figure 4). A bridge portion (interior of spike) is formed

integrally with the main portions and disposed between the main portions to join the main portions together, wherein the fluid transferring passage 68 is defined between the main portions.

As to claim 6, see the rejection of claim 1, supra. Elias discloses the spike 18 has an approximately cylindrical shape and solid structure, the top end surface of the spike (Figure 3, at spike top 62 abutting 50a), being an approximately hemispherical surface, which is upwardly convex, the spike except the top end portion being formed in an approximately tapered shape in which the outside diameter becomes progressively smaller toward the top end.

As to claim 10, Elias discloses the bottom portion of the spike is inserted in and fixed to the housing (col. 5, line s35-42).

As to claim 11, Elias discloses the central portion of the bottom surface of the openable/closable portion 50 is made approximately flat and is opposed to the top end 62 of the spike across a gap. (Figure 1).

As to claim 12, Elias discloses a ring-shaped projection 20, which projects radially inwardly and is placed in abutment with the top end portion of the spike, is formed to extend around approximately the entire circumference of the inside surface of the top portion of the elastic seal (Figure 2).

As to claim 13, Elias discloses the elastic seal 16 except the openable/closable portion 50 and the bottom end portion (where fins are present) has a bellows-shaped shrinkable portion (defined by ridges 56, Figures 3 and 4).

As to claim 14, Elias discloses the top end surface of the housing 24 and the top end surface of the elastic seal 46 are made substantially flush with each other (Figure 1).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elias et al. USPN 5549566.

As to claims 7 and 8, Elias discloses at least 2 fins shown at the angled intermediate portions of the spike in Figures 3 and 4. It would have been an obvious matter of design choice to provide the spike with the claimed at least 3 fins, since such a modification would have involved a mere change in the number of fins, which is within the level of ordinary skill in the art. The fluid transferring passages 68a are defined between adjacent ones of the fins.

As to claim 9, Elias discloses a portion of the elastic seal 16, abuts the fins, but does not present a polygonal cross section. It would have been an obvious matter of design choice to provide the article of Elias with polygonal shape, since such a modification would have involved a mere change in the shape of the component. A change in shape is generally recognized as being within the level of ordinary skill in the art. *In Re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966)

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline F. Stephens whose telephone number is (571) 272-4937. The examiner can normally be reached on Monday-Friday 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Jacqueline F Stephens
Primary Examiner
Art Unit 3761

May 9, 2007